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| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 06275-0160002 | Application No. 09/993,669 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) | | Applicant Ann-Kristin Karlsson et al. | |
| | | Filing Date November 27, 2001 | Group Art Unit 1623 |
| (37 CFR §1.98(b)) | | | |

| Other Documents (include Author, Title, Date, and Place of Publication) | | |
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| Examiner Initial | Desig. ID | Document |
| | 1 | Product description for Rhinocort Aqua® (budesonide), Nasal Spray 32 mcg, 2 pages, dated 01/05 |
| | 2 | Pulmicort Turbuhaler® (budesonide inhalation powder), 4 pages, dated 10/06 |
| | 3 | Astra Draco Specification for micronized budesonide prepared for use in the Rhinocort Aqua® nasal spray product, 2 pages, dated 11/20/95 |
| | 4 | Astra Draco Specification for budesonide prepared for use in the Pulmicort Turbuhaler® product, 2 pages, dated 04/01/97 |
| | 5 | US Pharmacopeia 23/NF18, pages 1686-1690 and 1963-1975, published by United States Pharmacopeial Convention, Inc., Rockville, MD (1995) |
| | 6 | Specification for Pulmicort Respules®, 3 pages, GEL Version ID: RITA.000-243-420.3.0, printed on 06/15/08 |
| | 7 | US Pharmacopeia 23, "Microbial Limit Tests" USP <61>, pages 1681-1686, published by United States Pharmacopeial Convention, Inc., Rockville, MD (1995) |
| | 8 | Astra Draco Specification for PULMICORT 200 TURBUHALER®, 5 pages, dated 09/17/97 |
| | 9 | Astra Draco Specification for RHINOCORT® nasal spray, 1 page, dated 04/225/91 |
| | 10 | "Guidance for Industry: Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 4 pages, November 2001 |
| | 11 | Pulmicort Respules® (budesonide inhalation suspension) product information, 6 pages, dated 6/07 |
| | 12 | Astra Draco Specification for Pulmicort® suspension for Nebulizing product, 2 pages, dated 02/23/1994 |
| | 13 | Recorded minutes of a 11/20/96 pre-NDA meeting attended by Astra USA, Astra Draco, and FDA officials, 6 pages |
| | 14 | Astra Draco Specification for "budesonide micronized sterile", 2 pages, dated 11/18/1983 |
| | 15 | Astra Draco documentation (in Swedish) of Manufacturing Method for Preferid® cream dated 09/09/1980, 5 pages, and English translation, 5 pages |
| | 16 | Internal Astra Draco document "Establishment of limits for content and related foreign steroids in budesonide substance" dated 03/26/1980, 5 pages |
| | 17 | Internal Astra Draco document "Limits for content and related foreign steroids in budesonide substance," dated 11/04/1980 |
| | 18 | Internal Astra Draco document "Analytical Certificate", dated 08/28/1980, in Swedish, 1 page, with English translation, 1 page |
| | 19 | Internal Astra Draco document "Analytical Certificate", dated 09/14/1978, in Swedish, 1 page, with English translation, 1 page |
| | 20 | Internal Astra Draco document "Analytical Certificate", dated 02/28/1980, in Swedish, 1 page, with English translation, 1 page |
| | 21 | Internal Astra Draco document "Analytical Certificate", dated 02/28/1980, in Swedish, 1 page, with English translation, 1 page |
| Examiner Signature | | Date Considered |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | |

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| Examiner Initial | Desig. ID | Document |
| | 22 | Internal Astra Draco document "Analytical Certificate", dated 03/28/1980, in Swedish, 1 page, with English translation, 1 page |
| | 23 | Internal Astra Draco document "Analytical Certificate", dated 03/28/1980, in Swedish, 1 page, with English translation, 1 page |
| | 24 | Internal Astra Draco document "Analytical Certificate", dated 06/09/1980, in Swedish, 1 page, with English translation, 1 page |
| | 25 | Internal Astra Draco document "Analytical Certificate", dated 05/04/1979, in Swedish, 1 page, with English translation, 1 page |
| | 26 | Internal Astra Draco document "Analytical Certificate", dated 05/04/1979, in Swedish, 1 page, with English translation, 1 page |
| | 27 | Internal Astra Draco document "Analytical Certificate", dated 05/08/1979, in Swedish, 1 page, with English translation, 1 page |
| | 28 | Internal Astra Draco document "Analytical Certificate", dated 12/12/1978, in Swedish, 1 page, with English translation, 1 page |

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